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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

DEES, NIKKI H

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/590,608	Applicant(s) JOHNSON ET AL.	
	Examiner Nikki H. Dees	Art Unit 1781	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed December 6, 2010, has been entered. Claims 1-37 are currently pending in the application. The previous 112 rejections of claims 1, 11, 13, 15, 22 and 23 have been withdrawn in view of the amendments to claims 1, 11, 13, 15, 22 and 23. The previous 112 rejections of claims 8, 20, and 21 have been withdrawn in view of Applicant's arguments. The previous 102(e) rejection over Johnson et al. has been withdrawn in view of the 1.132 declaration showing the invention of the prior art was not by another.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

Art Unit: 1781

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf (WO 99/13734) in view of Shiroyama et al. (6,328,982) and Pelan et al. (WO 03/043431) with evidence provided by "GRAS Flavoring Substances 20" (Food Technology. 2001. GRAS Flavoring Substances. Vol. 55. pp. 34-48) and "GRAS Flavoring Substances 21" (Food Technology. 2003. GRAS Flavoring Substances. Vol. 57. pp. 46-59).

5. Regarding claims 1, 7, and 30, Wolf et al. teach a confection in the form of a chewing gum comprising physiological cooling agents. Specific cooling agents taught for inclusion in the invention include isopulegol (i.e. 2-isopropenyl-5-methylcyclohexanol) (p. 17 lines 6-7).

6. Regarding claim 2, the confection of Wolf et al. comprises menthol.

7. Regarding claims 3-6, Wolf teaches the treatment of the cooling agents to control their release by methods including encapsulation in the form of spray-drying and fluid bed coating, as well as extrusion (p. 8 lines 10-21).

8. Regarding claims 9, 10, and 22, Wolf et al. teach the physiological cooling agents present in a coating on a chewing gum (i.e. confection) (p. 8 lines 29-30).

9. Regarding claims 11-13, the composition of Wolf et al. comprises at least 0.001% (i.e. 10 ppm), preferably more than 0.01% (100 ppm) cooling agent (p. 19 lines 4-7).

Art Unit: 1781

10. Regarding claims 14 and 16, additional cooling agents taught for inclusion in the invention of Wolf et al. include all of the cooling agents of claims 14 and 16 (pp. 16 and 17).

11. Regarding claims 18 and 33, the confection of Wolf et al. comprises a flavor in combination with the cooling agent (p. 19 lines 8-12)

12. Regarding claim 19, the composition further comprises menthol (p. 20 lines 1-6).

13. Regarding claims 20 and 21 to the ratio of physiological cooling agents to menthol, Wolf et al. teach that it is desirable to reduce the amount of menthol in a cooling composition to reduce the bitterness associated with high levels of menthol. Yet the menthol should not be replaced entirely, as it has distinct properties which are not found in other cooling agents (p. 27 lines 13-18). Wolf et al. go on to teach preferably about 50 to 70% menthol in their cooling composition (p. 32 lines 10-20).

14. Regarding claims 23 and 36, Wolf et al. teach a chewing gum composition comprising

a) about 5% to about 95% gum base;

b) about 5% to about 95% bulking agent and sweetening agent; and

c) about 0.1 to about 10% flavoring agent

where the flavoring agent comprises physiological cooling agents (claim 41).

15. Regarding claims 29, 32, 35, and 37, the physiological cooling agents present in the chewing gum of Wolf et al. further comprise menthyl succinate (claim 43).

16. Wolf et al. are silent as to their physiological cooling components comprising menthyl glutarate and p-menthane-3,8-diol, and compositions specifically requiring

Art Unit: 1781

these compounds as in instant claims 1, 8, 15, 28, 31 and 34. They are also silent as to ratios of menthol to cooling agents as required by claims 24-27.

17. Pelan et al. teach menthyl glutarate as a physiological cooling agent (p. 4 lines 21-26).

18. Shiroyama et al. teach p-menthane-3,8-diol as a physiological cooling agent (Abstract).

19. It would have been obvious to include menthyl glutarate and p-menthane-3,8-diol as physiological cooling agents in the composition of Wolf et al. as “[I]t is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art.” *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). MPEP § 2144.06(I).

20. Further, it is noted that menthyl glutarate (FEMA 4006) and p-menthane-3,8-diol (FEMA 4053) did not achieve GRAS status until 2001 and 2003, respectively, after the invention of Wolf et al. As the compositions of Wolf et al. are intended to be chewed or otherwise consumed, one of ordinary skill would not have been inclined to include in the composition cooling compounds that were not GRAS.

21. Additional motivation for the inclusion of menthyl glutarate in the invention of Wolf et al. comes from the fact that all of menthyl glutarate, menthyl lactate and menthyl succinate are menthyl esters. As menthyl lactate and menthyl succinate are preferred cooling compounds taught for use in the invention of Wolf et al., it would have been

Art Unit: 1781

obvious to utilize other menthyl esters known to be cooling compounds in the invention of Wolf et al.

22. It is known in the art that different cooling agents have different cooling intensities, cooling durations, and flavor profiles. Wolf et al. teach nearly 300 different formulations of cooling compositions and confections comprising the compositions, indicating that varying the amounts of the different components present in cooling compositions is part of the routine of one of ordinary skill in the art.

23. The improvement claimed by the instant invention, wherein cooling compounds not previously disclosed in the prior art of Wolf et al., but known in the art at the time of the instant invention as cooling compounds, are employed for their intended use as cooling compositions where an extensive number of cooling compositions are taught to be suitable is considered to be no more than a predictable use of prior art elements according to their established functions.

24. Regarding the ratios of the cooling components as required by claims 24 and 25, it would have been obvious to provide cooling compounds including menthyl glutarate (a menthyl ester) and isopulegol in the cooling compositions of Wolf et al. at a 1:1 ratio, as Wolf et al. teach menthyl esters (e.g. menthyl lactate) in 1:1 combinations with other cooling agents (e.g. Table 5). As noted by Wolf et al., different cooling compounds have different release rates and may be blended to maximize their cooling contributions (p. 38).

25. Regarding the ratio of cooling components as required by claims 26 and 27, it would have been obvious to provide cooling compounds including menthyl glutarate (a

Art Unit: 1781

menthyl ester) and isopulegol in the cooling compositions of Wolf et al. at a ratio of about 40:3 as Wolf et al. teach menthyl esters (e.g. menthyl lactate and menthyl succinate) in about 40:3 combinations with other cooling agents (e.g. Table 15, Example 52). Further, Wolf et al. again notes that different cooling compounds have different release rates and may be blended to maximize their cooling contributions and minimize the bitterness of the composition (p. 44). This optimization would have been routine to one of ordinary skill in order to provide cooling compositions and would have been expected to provide cooling compositions having a ratio of cooling compounds as claimed.

Response to Amendment

26. The declaration under 37 CFR 1.132 filed December 6, 2010, is sufficient to overcome the rejection of claims 1, 2, 7, 11-16, 18, 19, 23-25, 28-33, 36, and 37 based upon 102(e) over Johnson et al. (US 2004/0141927).

Response to Arguments

27. Applicant's arguments filed December 6, 2010, have been fully considered but they are not persuasive with regard to the 103 rejections.

Art Unit: 1781

28. The previous 112 rejection of claims 8, 20, and 21 has been withdrawn in view of the definition of physiological cooling agents as provided for in Applicant's specification at [0045].

29. Applicant argues that specific combinations of isopulegol, menthyl glutarate and menthanediol provide a cooling effect similar to that of WS-23 (Remarks, p. 9).

30. This argument is not persuasive. Initially, Applicant's independent claims are to a generic blend of menthyl glutarate, isopulegol and menthane diol, with the presence of menthol and other physiological cooling agents also claimed. As all of the claimed cooling agents are known in the prior art as cooling agents, to combine them in order to provide a cooling composition remains obvious as all of the compounds are being employed for their art recognized purpose to provide a predictable result.

31. Claims narrowing the amounts of the menthyl glutarate, isopulegol and methane diol (e.g. claims 17, 26, and 27) are considered obvious over Wolf as detailed in the rejection above as Wolf teaches menthyl esters in combination with other physiological cooling agents in ratios as claimed. The obvious starting point in determining the amount of the menthyl ester menthyl glutarate to include in combination with other cooling agents would be a ratio in line with where other menthyl esters are taught to be employed.

32. Applicant argues the surprising unexpected results from the claimed combination of cooling components (Remarks, p. 10).

33. As evidenced by Wolf, it is common in the art to employ a variety of cooling agents in combination in confections to provide the desired cooling sensation. The

Art Unit: 1781

arrival at a blend of cooling agents to replace a known cooling agent is not considered to be an unexpected result. Common motivation in the art is to provide blends of cooling agents be used in place of menthol to minimize or eliminate entirely the harsh characteristics associated with menthol while maintaining the characteristic cooling attributes of menthol. By extension, to provide a blend of cooling agents to with properties similar to another old and well known cooling agent (i.e. WS-23) is considered to be routine to one of ordinary skill in the art and not evidence of unexpected results.

Conclusion

34. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Art Unit: 1781

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikki H. Dees whose telephone number is (571)270-3435. The examiner can normally be reached on Monday-Thursday 8:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/N. H. D./

Nikki H. Dees
Examiner
Art Unit 1781

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